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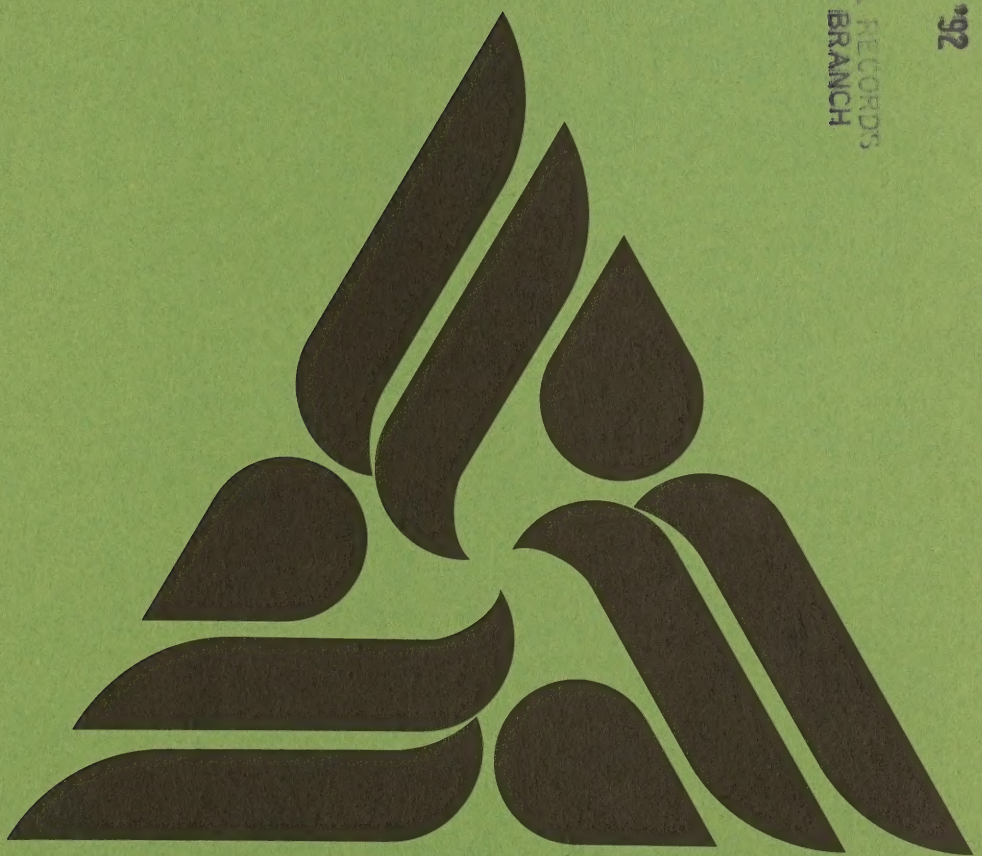
Minutes

Agricultural Biotechnology Research Advisory Committee

May 22-23, 1991



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UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE
MINUTES OF MEETING
May 22-23, 1991

TIME, PLACE, AND PARTICIPANTS

A meeting of the Agricultural Biotechnology Research Advisory Committee (ABRAC) took place on May 22 and 23, 1991, in the Cabinet Room of the Governors' House Holiday Inn at 17th Street and Rhode Island Avenue, N.W., Washington, DC. The meeting had been announced in the Federal Register and it was open to the public.

Members present included:

Bennie Osburn, Chair, University of California, Davis, CA;
Ann Sorensen, American Farm Bureau Federation, Park Ridge, IL;
Lee Bulla, University of Wyoming, Laramie, WY;
Harold Hafs, Merck, Sharp, & Dohme Laboratories, Rahway, NJ;
William Witt, Food and Drug Administration, National Center for Toxicological Research, Jefferson, AR;
Hugh Bollinger, TerraTek, Inc., Salt Lake City, UT;
Frank Whitmore, Ohio State University, Wooster, OH;
Sue Tolin, Virginia Polytechnic and State University, Blacksburg, VA;
John Kemp, New Mexico State University, Las Cruces, NM;
Edward Korwek, Hogan and Hartson, Washington, DC;
George Hill, Meharry Medical College, Nashville, TN;
Anne Vidaver, University of Nebraska, Lincoln, NE;
Deborah LeTourneau, University of California, Santa Cruz, CA;
Daniel Jones, Acting Executive Secretary and Deputy Director, USDA Office of Agricultural Biotechnology, Washington, DC.

U.S. Department of Agriculture (USDA) Office of Agricultural Biotechnology (OAB) staff present included Maryln Cordle, Martha Steinbock, Paul Stern, Barry Stone, Jim Staton, and Susan Flack. Others present are listed in Appendix A.

May 22, 1991

Call to Order, Approval of Agenda and Minutes

Dr. Bennie Osburn called the meeting to order at 9:15 a.m. He welcomed ABRAC members, OAB staff, and guests and asked everyone present to introduce themselves.

Dr. Osburn asked for changes or additions to the agenda. Dr. Daniel Jones suggested that because Ms. Martha Steinbock was leaving for Japan on May 23, her presentation be given on May 22 rather than May 23. Dr. Osburn agreed, and the agenda was approved with that change.

Dr. Osburn asked if there were additions or corrections to the minutes of the last ABRAC meeting. Dr. Sue Tolin said that she had some minor changes, and Dr. Jones noted that Dr. Hugh Bollinger also had suggested some revisions. With those changes, the minutes were approved.

Dr. Osburn welcomed Dr. Deborah LeTourneau, who had recently returned from a sabbatical to New Guinea, Borneo, Thailand, Central Asia, and Malawi.

Comments on the Guidelines

Dr. Osburn asked Mr. Paul Stern to summarize the public comments on the "USDA Proposed Guidelines for Research Involving Planned Introduction into the Environment of Organisms With Deliberately Modified Hereditary Traits" (henceforth referred to as the Guidelines) published in the Federal Register (56 FR 4134, February 1, 1991).

Mr. Stern reported that he and other OAB staffers were still organizing and categorizing the comments, and that any quantifications he discussed were only preliminary. He said that the important issues raised by the comments included:

1) Clarity of purpose: Many people wanted to know how the Guidelines would be used.

2) Support for the Guidelines: Many people asked whether the Guidelines were so costly and complicated that the competitive advantage of the United States in biotechnology research would be adversely affected.

3) Definitions and terms: Many people wondered why the terms "deliberately modified hereditary traits" and "introduction into the environment" were used instead of the terms "genetically modified" and "field testing," respectively.

4) Scope of the guidelines, particularly the exclusions.

5) Safety level of the parental organism: some support of the concept, but considerable criticism of the number of levels.

6) Attributes of the organism: Considerable concern about the complexity of the questions and whether every question would have to be answered in order to ensure compliance with the Guidelines.

7) Safety levels: Some people favored compressing the five levels in the Guidelines to only three, while other people called for more detail on safety levels 2, 3, and 4.

8) The safety levels in Appendix 1 drew some criticism.

9) Appendix 2 on confinement drew criticism.

10) Implementation: Some commentators wished the Guidelines to be mandatory, while others wanted them to remain voluntary. Considerable support was expressed for the Institutional Biosafety Committees (IBC's).

Dr. Harold Hafs asked when a summary of the comments would be completed. Mr. Stern replied that a summary should be available in a matter of weeks.

Dr. Frank Whitmore asked how the Department's responses to the comments were disseminated. Ms. Maryln Cordle responded that the final notice on the Guidelines in the Federal Register would summarize the comments and give the Department's responses.

Dr. David MacKenzie noted that if comments to a proposed Federal regulation called for minor changes, a final rule in the Federal Register was sufficient. However, if comments called for major changes, a new proposal and comment period were needed. Ms. Cordle responded that those requirements applied strictly only to regulations, and that the Guidelines were not considered regulations.

Dr. Osburn asked Dr. Hafs, Dr. Tolin, and Dr. Lee Bulla for their reactions to the comments.

Dr. Hafs said that most of the comments were predictable, and that many were heartening, thoughtful, and useful. He grouped the comments into two categories:

1) People who worried about the lack of implementation procedures or enforcement mechanisms for the Guidelines. These people also wanted to see the Guidelines become mandatory.

2) People who feared the Guidelines would create too much paperwork. He noted that such comments came predominantly from faculty at Cornell University, the University of California, and Iowa State University, and he speculated that the comments from those institutions may have been coordinated to some extent.

Dr. Hafs specifically noted the following individual comments: concern about how the Guidelines would affect small institutions that could not tap local expertise and a warning that USDA should not abrogate its oversight responsibilities in such instances; concern that if the Federal government relinquishes oversight responsibilities in biotech research, states will assume the oversight role -- and that a patchwork of uncoordinated rules and regulations will result; a suggestion that the U.S. guidelines be harmonized with those of the European Community (EC); speculation

that the comments would be very different if the Guidelines were characterized as mandatory rather than voluntary; and concern that USDA's jurisdiction in this matter overlaps with those of other Federal agencies.

Dr. Tolin also found the comments predictable, and said that it was sobering to see what other people thought of ABRAC's work. She said the comments indicated that there still is a role for the Guidelines, and indicated surprise that there were not more comments regarding the issue of overlapping jurisdiction.

Dr. Tolin interpreted the comments to indicate that the IBC's want more help, and that USDA needs advice on the Guidelines' scope and implementation. In addition, she said, more specificity is needed. The public interest groups' comments, in her view, indicate that the public's role is unclear in this version of the Guidelines. Dr. Tolin noted that the comments were evenly split between positive and negative feedback. The task ahead, she said, is to sort out the comments and see where the Guidelines need to be changed.

Dr. Jones noted that Dr. John Kemp and the Classification and Confinement Working Group had met the previous day to discuss some of the issues that Dr. Tolin mentioned.

Dr. Bulla expressed the view that the comments represented a mixed and spotty response to the Guidelines. He would have liked to have seen responses from a broader range of groups -- but the spottiness may have been due to the Guidelines' voluntary nature. If the Guidelines become mandatory, heated debate is likely, he said. Dr. Bulla added that, based on the comments, the following issues need more attention: implementation; oversight; roles of the IBC's and ABRAC; title of the Guidelines and selected terminology; mandatory versus voluntary nature of the Guidelines; confinement procedures; and exclusions and exemptions.

Dr. Bulla expressed the view that ABRAC needs to respond to the comments publicly. He said that the Guidelines were receiving publicity, and that ABRAC might be receiving unfair blame for the Guidelines' shortcomings.

Dr. Hugh Bollinger said that there is considerable anguish in the research community over the Guidelines. The additional paperwork generated by the Guidelines could worsen agricultural biotechnology's current status as a stepchild of pharmaceutical biotechnology -- and that could reduce the number of people willing to conduct agricultural biotechnology research.
Dr. Bollinger also noted that the Competitiveness Council chaired by Vice President Dan Quayle was dealing with biotechnology.

Dr. Letourneau contrasted the view of the guidelines as generating paperwork with a broader view of the guidelines as stimulating useful research that could help to support future decisions, exemptions and exclusions.

Dr. Kemp noted that the Guidelines attracted comments from people who previously had not taken the idea of such guidelines seriously: the Agricultural Experiment Stations, and traditional breeders' groups. These people, in his view, panicked when they saw the Guidelines because they had not kept abreast of current developments in biotechnology.

Ms. Steinbock noted that an effort to harmonize regulation of U.S. biotechnology research with that of the EC, the Organization for Economic Cooperation and Development (OECD), and individual countries was underway. While actual harmonization might not be possible, the scientific principles underlying such regulations could be coordinated.

Legal Basis for the Guidelines

Dr. Hafs asked if the legal basis for the Guidelines had been questioned. Dr. Jones replied that the Office of Management and Budget (OMB), the Council on Environmental Quality (CEQ), and USDA's Office of General Counsel (OGC) had reviewed the Guidelines before they were published in the Federal Register. Ms. Cordle noted that the Guidelines were published as a scientific principles document, and did not cite any statutory authority for specifying any prescriptive requirements. For that reason, legal issues will not enter the picture until the Guidelines are implemented.

Dr. Bulla asked whether legal problems would result if a researcher made a mistake, but said he or she was following the Guidelines. Ms. Lisa Zannoni responded that funding a research project entails acceptance of responsibility by a funding agency, but the Guidelines were intended simply as points to consider.

Dr. Bulla expressed the view that separating implementation of the Guidelines from the Guidelines themselves was a big mistake because of legal problems that could arise. Dr. Kemp disagreed, saying that if any researcher tried to blame the Guidelines at this point for problems in an experiment, he or she would simply be evading responsibility for his or her own decision-making.

International Issues

Dr. Osburn invited Ms. Steinbock to update the Committee on international agricultural biotechnology issues.

Ms. Steinbock summarized the goals of ongoing international activities related to agricultural biotechnology as:

1) Promoting a common understanding of how agricultural biotechnology can help deal with the challenges of agriculture and forestry;

2) Reaching international agreement on the scientific principles which underpin regulatory decisions;

3) Creating a free global market where biotechnology products are traded based on established, scientifically based criteria such as safety, efficacy and quality; and

4) Identifying opportunities for research cooperation which reap the maximum benefit for U.S. agriculture.

The USDA agencies involved in international activities include Office of Agricultural Biotechnology (OAB), Agricultural Research Service (ARS), Animal and Plant Health Inspection Service (APHIS), Cooperative State Research Service (CSRS), Foreign Agricultural Service (FAS), Forest Service (FS), and the Office of International Cooperation and Development (OICD).

Ms. Steinbock described several kinds of international biotechnology activities including 1) bilateral policy discussions, 2) bilateral regulatory discussions, 3) symposia and workshops, 4) collaborative research, scientific, and technical exchanges, and 5) participation in international organizations, including a) the U.S.-EC Task Force on Biotechnology Research, b) the U.S.-EC Permanent Technical Group on Biotechnology and the Environment, c) the General Agreement on Tariffs and Trade (GATT) sanitary and phytosanitary discussions, d) the OECD Group of National Experts on Biosafety and Biotechnology, and e) other groups and organizations including the Food and Agriculture Organization of the United Nations (FAO), and United Nations Conference on Environment and Development (UNCED).

Dr. Jane Rissler of the National Wildlife Federation asked if any of the aforementioned activities include discussions of benefits analysis. Ms. Steinbock answered that they do, noting that the U.S. and EC are talking about how to communicate with the public about biotechnology, and that an OECD group is developing a paper that includes a section on the economic and social benefits of agricultural biotechnology. Benefits analysis, she said, is also at the forefront of discussions of biotechnology with less developed countries (LDC's).

Dr. Sally McCammon, APHIS, noted that the interests of industrialized countries and LDC's regarding agricultural biotechnology differ greatly. Industrialized countries often are concerned with limiting the environmental impacts of biotechnology, while LDC's see biotechnology as a way to achieve needed increases in food production. She added that the United States is trying to be proactive in developing avenues of international cooperation in agricultural biotechnology.

Dr. MacKenzie referred to the United Nations Code of Conduct discussions. He noted that FAO does not want the Code to be

mandatory, and that the organization does not have the legal authority to enforce the Code.

Dr. Hafs asked why Ms. Steinbock thought the goal of harmonizing different countries' biotechnology regulations is unrealistic. Ms. Steinbock replied that the answer depends on what is meant by harmonization. If by harmonization one means that trade is made possible, she said, then harmonization is a realistic goal. If harmonization means creating a supranational set of guidelines, harmonization is unrealistic because individual countries already have their own legal structures and systems against which a single set of guidelines is bound to clash. Dr. Hafs recommended that the goal of harmonization not be abandoned, because such abandonment would preclude international research collaboration.

Dr. Tolin noted that the OECD is working toward harmonizing the scientific principles that underlie biotechnology, and that each country has to work within its own regulatory framework.

Dr. George Hill asked Ms. Steinbock if any work was being done with Japan. Ms. Steinbock replied that the United States and Japan have a Scientific and Technical Agreement. The agreement took five years to negotiate, mainly due to difficulties in dealing with intellectual property issues. Under the agreement, USDA does not have a memorandum of understanding with its Japanese counterpart, and Ms. Steinbock said that more needs to be done to further U.S.-Japanese cooperation in the biotechnology area.

Implementation of the Guidelines

Dr. Osburn invited Ms. Lisa Zannoni, assistant to the Assistant Secretary for Science and Education, to update the ABRAC on efforts to implement the Guidelines.
Ms. Zannoni reported that implementation of the Guidelines is contingent upon completion of the following four objectives:

1) Completion of Departmental responses to public comments on the Guidelines;

2) Emplacement of mechanisms for implementing the Guidelines.

3) Completion of the National Environmental Policy Act (NEPA) regulations for CSRS; and

4) Resolution of the scope issue for biotechnology guidelines and regulations;

Ms. Zannoni noted that she chairs the USDA group charged with creating an implementation plan that assures the public that biotechnology research will be reviewed adequately, but also minimizes the workload on the research community. Members

include representatives from FS, ARS, CSRS, APHIS, and OAB. She indicated that the implementation group has drafted options which are currently under review.

Ms. Zannoni said that the funding regulations will be amended to stipulate that compliance with the Guidelines is required in order for research projects to receive USDA funding.

Ms. Zannoni referred to the Competitiveness Council report, which called for Federal guidelines to contain performance standards for research institutions, rather than design standards. Ms. Zannoni, on behalf of Assistant Secretary Hess, requested that the ABRAC advise USDA on what performance standards for institutions reviewing and performing research should be. She said the performance standards will be the basis for future USDA programs for the IBC's. After the performance standards are completed, Ms. Zannoni said her group will finalize its implementation recommendations for clearance by OGC, Dr. Hess, and OMB.

Dr. Bulla asked Ms. Zannoni if she wanted the ABRAC to advise how the IBC's will do performance standards. Ms. Zannoni replied that instead of saying what types of experts need to sit on IBC's, the implementation plan must state what the IBC's must be able to do. Dr. Kemp observed that using performance standards instead of design standards shifts more responsibility to the institution.

Dr. Bulla asked who would resolve differences if five institutions with the same projects came up with a different set of standards. Ms. Zannoni said USDA would set the performance standards.

Ms. Cordle observed that an institution would certify that it complies with either National Institutes of Health (NIH) or USDA standards, but that compliance with those standards can be achieved in any number of different ways.

Dr. Tolin noted that an IBC can send to the ABRAC for approval any proposed research project that the IBC cannot approve on its own because of a lack of expertise. Dr. Kemp predicted that university presidents concerned about legal liability will tell researchers to have the Federal government approve every project. Dr. Tolin agreed that that might happen until the universities develop sufficient experience to approve proposals themselves.

Dr. Rissler asked whether the public outside the university community would have a chance to participate in the project approval process. Ms. Zannoni replied that an effort was made to work a public participation component into the performance standards. In addition, she said, NEPA includes public participation, but public participation is not incorporated into the Guidelines.

Dr. Rissler then asked when implementation of the Guidelines would be completed. Ms. Zannoni estimated that the final implementation plan would go to OMB in a month, and into the Federal Register at a later time. Dr. Rissler said the public should have the chance to comment again on the Guidelines when implementation is proposed.

Dr. Hafs asked whether USDA would undertake some of the training of IBC members. Ms. Zannoni replied that the Department plans to do so, adding that USDA training would help to assure uniformity among the IBC's. However, she said, money is needed to pay for such training. Ms. Zannoni stressed that USDA needs help from the ABRAC in designing performance standards for institutions, rather than IBC's.

Dr. Bollinger asked whether the Competitiveness Council would look at the final implementation plan. Ms. Zannoni replied that she did not know.

Dr. Rissler asked who gives final approval for agricultural biotechnology research projects. Dr. MacKenzie replied that each institution provides a statement of assurance that it has complied with the necessary guidelines and policies. Dr. Rissler asked if USDA looks at the reviews from the IBC's. Dr. MacKenzie replied usually not, and reiterated that USDA only checks for the IBC certification of compliance with necessary guidelines. Ms. Zannoni said that CSRS, as the funding agency, has final approval authority for a project.

Dr. Rissler asked if the Guidelines themselves constitute performance standards. Ms. Cordle replied that they do with the possible exception of Appendix 2. Ms. Cordle added that during the review process some considered Appendix 2 as design standards even though USDA says the measures contained in that Appendix are examples only and not prescriptive.

Dr. Osburn appointed a work group to develop ideas on performance standards including Drs. Whitmore, Tolin, and LeTourneau and Mr. Stern, with Dr. Whitmore as chair.

The ABRAC recessed for lunch at 12:00, and reconvened at 1:25 p.m.

USDA Request for Proposals on Biotechnology Risk Assessment Research

Dr. Osburn introduced Dr. MacKenzie, who described the development of a USDA request for proposals on biotechnology risk assessment research.

Dr. MacKenzie began by noting that the 1990 Food, Agriculture, Trade, and Conservation Act (hereafter referred to as the 1990 Farm Bill) contained a provision dealing with the assessment of

risk in biotechnology research. Section 1668 of the 1990 Farm Bill establishes a risk assessment research program for agricultural biotechnology, and sets aside 1 percent of USDA's biotechnology research budget to pay program expenses. However, the statute does not define biotechnology -- and the scope of that definition directly affects the base from which the 1 percent is calculated.

Dr. MacKenzie reported that he had earlier convened an interagency group consisting of representatives from the U.S. Environmental Protection Agency (EPA), APHIS, OAB, ARS, FS, and non-Federal interest groups such as environmental groups to discuss how to implement Section 1668. The discussions resulted, he said, in the recommendation of a five-step process for soliciting proposals:

1) First, a broad solicitation of researchable questions in biotechnology risk assessment -- a kind of "wish list" of research topics -- from sources such as Federal agencies, ABRAC, and the concerned public;

2) Second, distribution of the list to the public via publication in the Federal Register and mailings to scientists;

3) Third, review of research proposals by a multi-agency committee that would call attention to proposals that relate most directly to topics on the list;

4) Fourth, a normal peer review and recommendations by the peer review panel that include merit-based rankings of proposals identified in Step #3, resulting in final recommendations to CSRS; and

5) Finally, electronic submission by the collectors of biotechnology risk assessment data for inclusion in a CD-ROM database.

Dr. MacKenzie said the amount of money available for such a program is still unknown because biotechnology has not been defined for funding purposes. A common figure, he said, is $1.4 million, based on a USDA research funding level of $140 million annually, according to one definition. However, Congressional intent in setting up the program must be determined before the funding level can be determined more precisely.

In answer to a question by Dr. Osburn, Dr. MacKenzie said the grants may be handled in much the same way CSRS handles water quality grants. In answer to a question by Dr. Hafs, Dr. MacKenzie said that USDA's Economic Research Service (ERS) would probably not participate in the program because ERS doesn't deal directly with risk assessment per se.

Dr. Osburn asked if the ABRAC or an ABRAC working group could help in the process. Dr. MacKenzie replied that ABRAC assistance would be most helpful.

Dr. Kemp emphasized the importance of an ABRAC working group in this area having access to data being generated currently in field tests. Dr. MacKenzie agreed and described some of the plans of the NBIAP program for making such data available.

Dr. Osburn thanked Dr. MacKenzie for his report. Dr. Osburn invited Dr. Kemp to report on the deliberations of the ABRAC's Classification and Confinement Working Group which had met the previous day.

Classification and Confinement Working Group Report

Dr. Kemp reported that the Classification and Confinement Working Group (hereafter referred to as the Group) meeting of the previous day had focused on refining and reorganizing the Guidelines' classification and confinement procedures in light of public comments on the Guidelines. He noted that the public comments focused on Appendices 1 and 2, and on classification and confinement procedures.

Dr. Kemp reported that the Group recommended reducing the number of levels of safety concern in the Guidelines from five to three. Safety level 1 would be for experiments which pose no safety concern. Safety level 2 would combine the old levels 2, 3, and 4, and would be for those experiments which present a recognized but manageable risk. Safety level 3 would replace the old safety level 5, and would be for those experiments which not only present significant risk, but for which there are no known effective management procedures other than total containment.

The Group, said Dr. Kemp, also agreed to institute two confinement levels instead of the four specified in Appendix 2. The first confinement level would consist of good agricultural research practices. The second confinement level would add confinement procedures appropriate for the organism sufficient to reduce an experiment's level of safety concern to a level equivalent to safety concern Level 1.

The Group also defined parental organism as the starting, unmodified organism in an experiment, according to Dr. Kemp.

Dr. Kemp noted that the Group had discussed whether to retain all five of the parental organism attributes described on page 4139 of the Guidelines. The decision was to keep all five, but to interchange the first two attributes.

Dr. Kemp said that the Group agreed that a new cross-reference to the definition of "accessible environment" in Section VI-A should be added to Section VI, Step 1.

Dr. Kemp noted that, at his request, Ms. Cordle had drafted some changes in Section VI-D, Action IV, Levels of Safety Concern and Section VIII. Those changes were as follows:

Section VI-D. First paragraph, second sentence, add the phrase "and the manageability of those effects."

Section VI-D-1. Substitute, "Organisms and their traits whose attributes in the specified accessible environment are sufficiently well understood so that it can be determined with reasonable certainty that the organism has no potential for significant adverse effects on human health or on managed or natural ecosystems, even if dissemination is uncontrolled or unmanaged beyond the use of standard agricultural practices."

Sections VI-D-1-a through VI-D-1-g remain unchanged.

Sections VI-D-2, VI-D-3, and VI-D-4. Substitute new Section VI-D- 2, "Organisms and their traits that have potential for significant adverse effects on human health or on managed or natural ecosystems which are manageable, but that require confinement measures beyond the use of standard agricultural practices to prevent significant adverse effects."

Section VI-D-5. Substitute new Section VI-D-3 to read, "Organisms and their traits that have a potential for significant adverse effects on human health or on managed or natural ecosystems which cannot be adequately controlled or managed outside contained facilities to prevent significant adverse effects.

Section VI-D-5-a through VI-D-5-f text unchanged with new numbers VI-D-3-a through VI-D-3-f.

Ms. Cordle explained that the phrase "significant adverse effects" was used to distinguish from "trivial effects". "Organisms and their traits" was used to clarify interest not only in direct effects of the organism, but potential effects of gene transfer to other organisms as well. Dr. Korwek questioned whether traits have attributes and suggested some "word-smithing" is needed.

Ms. Cordle then discussed the following suggested changes in Section VII intended to: (a) address the "process" concerns and (b) interpretation about the phrase, "not well understood."

Section VII. First paragraph, third sentence would be changed to read, "The effects of the modification on safety must be evaluated with reference both to the direct actions of the organism and its traits on human health or the environment and to the indirect actions of the organism through the substances its produces.

The description of the three types of modification would be changed to read:

Section VII-A. "Type 1 modifications include those which delete or disrupt expression of a gene or genes known to be responsible for traits such as pathogenicity, fertility, survival, or fitness, in ways that increase safety of the organism and affect its manageability so that the modified organism is categorized in a lower level of safety concern."

Section VII-B-1. "Genetic modifications that have no phenotypic or genotypic consequence in the field, e.g., certain marker genes bearing no hazardous traits, and"

Section VII-B-2. "Genetic modifications that have known or predictable phenotypic or genotypic consequence(s) in the field that is unlikely to result in additional significant adverse effect on human health or on managed or natural ecosystems, e.g.,a storage protein gene with a more desirable amino acid balance."

Section VII-C-1 "Genetic modifications that affect the expression of genes, the functions or effects of which are sufficiently well understood to reasonably predict the consequence(s) of an organism or its trait(s) on managed or natural ecosystems, and"

Section VII-C-2 "Genetic modifications that have known or predictable phenotypic or genotypic consequence in the field that is likely to result in additional significant adverse effects on human health or on managed or natural ecosystems, e.g., those which result in the production of certain toxins."

Several members questioned the first proposed change in Section VII. Dr. Korwek suggested that rather than say "organism and its traits" it would be better to add an additional sentence clarifying that effects resulting from gene transfer are included.

Dr. Bulla, Mr. Korwek and Dr. Hill questioned why "genotypic consequence in the field" is included in the definition. After some discussion Dr. Kemp suggested that having identified a possible problem, the group move on to discussion of other issues.

Dr. MacKenzie asked Ms. Cordle whether she intended for "human health" consequences to be included in VII-C-1. She replied that it should be included for consistency. Dr. Vidaver pointed out that it was not included in the original.

Dr. Kemp discussed the Group's recommendations on Table 1 on page 4142. The revised table would be as follows:

Table 1. Determination of the Level of Safety Concern for the Modified Organism

Level of Safety Concern for the Parental Organism	Level of Safety Concern for the Modified Organism		
	Type 1 Modification	Type 2 Modification	Type 3 Modification
Level 1	Level 1	Level 1	Level 2 or 3
Level 2	Level 1	Level 2	Level 3
Level 3	Level 1 or 2	Level 3	Level 3

In response to Dr. Tolin's question about revision of Section VIII, Dr. Kemp indicated that the text in Section VIII would be changed to reflect the revised table. Committee members asked questions about specific aspects of the proposed changes.

Dr. Kemp turned the discussion to an explanation of the Group's recommendations about changes in confinements levels, reiterating the proposal for two levels of confinements as described above.

Dr. Sorensen pointed out that the group discussed under confinement level 1 adding the idea that elements of confinement are already part of good agricultural research practice. Dr. Tolin added that the inherent biology of the organism and its characteristics provide confinement without consciously applying extra practices. Dr. Bulla suggested that a glossary of terms might be useful.

Dr. Kemp presented the working group's suggested changes for the various attributes in Table 1, Appendix 1 (page 4144 of the Guidelines) as follows:

TABLE 1/APPENDIX 1
EXAMPLES OF DETERMINING LEVEL OF SAFETY CONCERN
FOR PARENTAL ORGANISMS

Parental Organism	Attributes					
	1	2	3	4	5	Overall
Cow	1	1	2	2	1	1
Clavibacter xyli	2	1	1	1	1	2
Rapeseed	2	2	2	2	1	2
Africanized honeybee	2	3	2	2	2	2
Foot and mouth disease	3	3	3	3	2	3

Dr. Bulla noted that columns 1 and 2 in Table 1, Appendix 1 should be interchanged to match the proposed changes in the text.

Dr. Kemp noted that the Group had discussed the appropriateness of the examples in Appendix 1, and that it had decided to footnote Table 1, Appendix 1 to inform readers where to obtain additional examples. He said the Group eventually wanted to revisit the examples and ask experts to review and edit the material in Appendix 1. Dr. Kemp also said that the Group wondered whether to take the examples three steps further -- beyond the parental organism through modification to the modified organism and choosing a level of confinement. He said the Group concluded that the additional steps would not be needed if the number of safety levels was reduced from five to three.

Dr. MacKenzie expressed concern with the Africanized honeybee example, because APHIS is trying to keep the insect out of the United States. Dr. Sorensen responded that the Africanized honeybee is already in the United States. Dr. MacKenzie expressed concern that the use of the Africanized honeybee as an example would alarm the public. Dr. Jones recalled that Dr. Fred Gould had previously developed a parasitic wasp example. Dr. MacKenzie said the parasitic wasp might be a better insect example.

Dr. Vidaver noted that the Group decided to add a footnote to Table 1, Appendix 1, and cross reference the appropriate section of the Guidelines, explaining that the overall level of safety concern is not the sum or mean of levels of safety concern for each of the attributes.

Dr. Bollinger asked how the final version of the Guidelines would be distributed to researchers. Ms. Zannoni responded that state agricultural experiment stations as well as other interested parties would receive copies of the Guidelines. Dr. MacKenzie added that the Guidelines will also be available on the NBIAP electronic bulletin board and that the grants application kit would contain a Guidelines quality assurance form.

Dr. Osburn recessed the meeting briefly, after which he introduced Dr. Charles Hess, Assistant Secretary of Agriculture for Science and Education.

Scope of the Guidelines

Dr. Hess first addressed progress on the scope definition (i.e., scope of organisms to receive oversight). He said the goals of defining the scope were to assure the public that the Federal government is overseeing the release of modified organisms into the environment and doing this without adding a tremendous regulatory burden on researchers and commercial developers.

Dr. Hess said originally the intent was to publish the Guidelines in the same time period as the OSTP scope definition so that people would see the scope definition and its application by an agency. That turned out not to be possible.

Dr. Hess said that OMB wants to minimize the impact of regulations on the public, a goal that he shares. However, he also believes that regulatory oversight is needed to build public confidence in biotechnology more quickly.

Dr. Hess explained that OMB's insistence on minimal regulatory impact forced USDA to agree to separate implementation of the Guidelines from their initial publication as principles in order to get timely publication. Ms. Zannoni, he said, has been working with USDA agencies to put together an implementation plan. Dr. Hess added that USDA will ask those investigators who are applying for grants to certify that they are using the USDA field release Guidelines.

Dr. Hess said that the Competitiveness Council is reviewing the comments received on the OSTP scope definition and he felt that comments received on scope for the Guidelines and ABRAC's reaction to those comments also would be helpful to USDA.

Dr. Osburn expressed appreciation to Dr. Hess and his staff in facilitating publication of the Guidelines.

Dr. Osburn reiterated that the ABRAC would be pleased to help USDA to design performance standards for institutions. Dr. Hess responded that perhaps an ideal IBC could be designed, but that USDA can't be dictating design standards to a university. That is why USDA will develop performance standards -- to tell the universities what they need to be able to do, and to allow them flexibility in how they carry it out.

Dr. Bulla asked how the Guidelines could be considered voluntary if USDA links compliance with the Guidelines to the release of Federal funds for research. Dr. Hess cited discussions with OMB as the reason that the Guidelines were characterized as voluntary in the Federal Register. Ms. Zannoni explained that the sentence characterizing the Guidelines as voluntary probably would be changed when implementation occurs.

Ms. Margaret Mellon of the National Wildlife Federation urged that the Guidelines be made mandatory. She said that efforts by OMB to cut back on regulations could put agricultural biotechnology programs at risk, because the public would not have confidence in the technology if USDA did not retain oversight responsibilities for such programs.

Ms. Mellon asked if Dr. Hess has any comment on the recent version of the scope definition leaked to the mass media. That definition said that the Federal government will not exert oversight over agricultural biotechnology research unless it demonstrates significant and substantial risk.

Dr. Hess said he felt constrained in commenting on an "internal document", but said he shares concerns expressed by others about that particular version.

Dr. Vidaver asked, under implementation of the Guidelines, who would have decision-making power. Ms. Zannoni said the IBC would conduct the review but the funding agency will make the final decision. Dr. Hess said his role would be in the "appeal" position.

ABRAC members expressed support for USDA training of IBC members on the Guidelines. Dr. Osburn noted that there is little interaction at this time between USDA and the IBC's. He suggested that the training of IBC members involve staffers from APHIS as well as from OAB and CSRS, and that an ABRAC subcommittee might look at this issue.

Dr. Kemp noted that Ms. Zannoni had said that IBC reviews were not mandatory, but that IBC performance standards would be. Dr. Hess said he personally thought that the IBC's would handle the USDA Guidelines in the same way they handle those of the National Institutes of Health (NIH). However, he added, if universities can meet the performance standards in another way, that would probably be acceptable.

After summarizing the day's developments for Dr. Hess, Dr. Osburn returned the discussion to the report of Dr. Kemp and the Classification and Confinement Working Group.

Classification and Confinement Working Group Report (Continued)

Dr. Kemp noted that the Group had edited the examples of confinement measures for domestic and terrestrial plants and made assignments for editing the other groups. He reported that the group discussed the appropriateness of the six categories but reached no decision at this time. He described the work the Group had done on domestic, terrestrial plants, and reported that the Group had agreed to separate the security measures from confinement measures throughout Appendix 2.

Dr. Kemp said the working group discussed how to organize the level 2 confinement practices but didn't come to closure on that issue.

Dr. MacKenzie endorsed the new approach and pointed out its consistency with software that NBIAP developed to help researchers in putting together an application.

Dr. Tolin suggested matching the practices with the types of confinement; i.e., physical, chemical, etc., and suggested the need to look at the reason for using a particular measure. She also suggested that perhaps a section on termination practices and monitoring may be worth considering. Dr. Tolin also suggested another look at confinement level 1 and perhaps some reordering. Dr. Vidaver suggested the need for clarification regarding termination practices for level 1.

Dr. MacKenzie advised that the Guidelines need to make clear that the confinement measures outlined in Appendix 2 are options rather than requirements. Dr. Tolin noted that the Guidelines do not currently inform researchers how stringent confinement measures must be to ensure USDA approval.

Dr. Kemp reopened a question raised earlier by Ms. Cordle as to the merit of carrying the examples of organisms in Appendix I through subsequent steps as a means of clarifying the assessment and confinement concepts.

Dr. Osburn suggested that perhaps we could have some volunteers to carry through the examples. Dr Whitmore and Dr. Tolin said this would be helpful. Dr. MacKenzie said he thought the solution might come through the training program.

Dr. Vidaver said she believed there was still no determination of when genetically-modified products, e.g., a transgenic cow or tomato, could be used for food or feed during the research stage of development. Dr. Hess indicated that we are waiting for an

opinion on transgenic tomato. Ms. Cordle questioned whether it is appropriate to address "food safety" and "food use" within the scope of this particular document. Dr. Vidaver said she thought something should be said giving guidance on this point.

Ms. Cordle suggested that some language might be added on page 4139, Section III-B, concerning FDA jurisdiction without implying "food additive" status for these products. Dr. Tolin expressed the view that investigators and IBCs might need some guidance under "good agricultural research practices" as to the food status of plants in a field trial. She contrasted the absence of food use restrictions in traditional plant trials with plant trials in which food use restrictions may be necessary and therefore need to be stated clearly. Ms. Cordle volunteered to consult with FDA and FSIS on how best to assure that the standard agronomic practice section would not be misleading with regard to food safety.

End-of-Day Remarks

Dr. Osburn asked Dr. Kemp to discuss the Group's recommendations at the meeting scheduled for the next day, and reminded Dr. Whitmore to bring suggestions for performance standards for institutions.

Dr. Jones discussed an effort by the Biotechnology Research Subcommittee (of which Dr. Hess is a member) of the Federal Coordinating Council on Science, Engineering, and Technology. He said the subcommittee is gathering data from a number of agencies on current and projected biotechnology research budgets. From that information, he said, the subcommittee will develop biotechnology research goals and priorities. The ultimate result could be a Federal biotechnology initiative, he added.

Dr. Sorensen asked if the subcommittee was looking at areas for Federal-private sector cooperation. Dr. Hess replied that the Competitiveness Council was looking at that issue.

Dr. Osburn assigned ABRAC members tasks for completion by the next day. He asked Dr. Vidaver to review the domestic, terrestrial plants component of Appendix 2 of the Guidelines. Dr. Hafs was asked to review the domestic, terrestrial animals component; Dr. Bulla, microorganisms; Dr. LeTourneau, insects; Drs. Hill and Witt, aquatic animals; and Dr. Bollinger, aquatic plants.

Dr. Kemp asked Ms. Cordle to re-edit her suggested changes.

Dr. Osburn recessed the meeting at 5:00 p.m.

Dr. Osburn reconvened the meeting at 9:15 a.m.

Effects of Making the Guidelines Mandatory

Dr. Bulla expressed concern that the Guidelines apparently were moving from voluntary to mandatory status. He said that this change in status would cause controversy and debate. In response to a question from Ms. Cordle, Dr. Bulla said he had thought the Guidelines would remain voluntary, and had not anticipated that receipt of USDA research money would be tied to compliance with the Guidelines.

Dr. Kemp said that the only way the Guidelines could have been published initially was to characterize them as voluntary, but that OAB's original intent was for the Guidelines to be mandatory. Dr. Osburn agreed. Dr. Kemp added that the Guidelines would not duplicate the work of regulatory agencies -- but if there was anything in agricultural biotechnology research that the agencies didn't cover, the Guidelines would.

Dr. Bulla said he personally had no problem with the Guidelines becoming mandatory, but he was concerned that the change from voluntary to mandatory status would be inflammatory in the research community. Dr. Tolin agreed that the characterization of the Guidelines as voluntary influenced the kinds of public comments USDA received, but that the voluntary characterization was the only way the Guidelines could have been published.

Dr. Kemp noted that the ABRAC had expressed reservations over the separation of the Guidelines from the implementation component. Ms. Cordle said that OAB had consulted with OGC and OMB about whether OAB should indicate its future intent to make the Guidelines mandatory for USDA funded research, but it was decided not to express that intent because a decision had not been reached. Dr. Bulla reiterated his concern that the research community should have been informed of the Department's intent.

Dr. Vidaver asked if the Guidelines are, in fact, going to become mandatory. Ms. Cordle replied that the implementation plan has not been approved; in fact, review of the plan is just beginning.

Ms. Cordle then asked if the ABRAC believed the scientific portion of the Guidelines should not be finalized until after comments were received and implementation was finalized. Dr. Hafs responded that Dr. Bulla's point was very important, and pointed out that in the public comments, Cornell University and the University of California opposed even voluntary use of the Guidelines. Dr. Hafs went on to say that another round of comments and perhaps a hearing is needed.

Drs. Kemp and Tolin agreed that another round of comments is needed.

Dr. Hafs moved that the ABRAC recommend to Dr. Hess that the revised Guidelines and implementation component be published simultaneously in proposal form for public comment. Dr. LeTourneau seconded the motion.

Dr. Bulla moved that the motion by Dr. Hafs be amended to substitute the phrase "together with" for the word "simultaneously." Dr. Tolin seconded Dr. Bulla's proposed amendment. The ABRAC voted 11-0 with one abstention to incorporate Dr. Bulla's amendment.

The ABRAC then voted 12-0 in favor of the motion by Dr. Hafs.

Recommendations of the Classification and Confinement Working Group

Dr. Osburn invited Dr. Kemp to revisit the recommendations of the Classification and Confinement Working Group (hereafter referred to as the Group).

Dr. Kemp expressed doubt that the ABRAC could make hard recommendations to change the Guidelines based on the suggestions of the Group. He suggested that any ABRAC recommendations resulting from the Group's work be in principle only.

Dr. Kemp moved that the intent of revisions of the Guidelines recommended by the Working Group on Classification and Confinement be approved as outlined by the Group. Dr. Whitmore seconded the motion.

Dr. Kemp summarized the basic intention of the Group to reduce the number of levels of safety concern from five to three. Level 1 would cover experiments that generated little safety concern and require only "good agricultural research practices." Level 2 would cover experiments that prompted some concern, but could be managed. Level 3 would cover experiments that generated safety concerns that are unmanageable at this time.

Ms. Cordle submitted a newly revised version of the changes she had prepared the previous day (Appendix B). She explained that these revisions were designed to reduce the number of levels of safety concern from five to three, and to change the focus of levels to determining whether there are significant adverse effects and whether they can be managed.

The group discussed the change proposed for the first paragraph of Section VI-D. It was agreed that the second sentence needs to indicate more clearly the two distinct bases for classification, which Ms. Cordle suggested can be done using (1) and (2) prefacing each point.

Dr. Tolin said "prevent" should be changed to "limit" or "minimize," because "prevent" is too absolute a term. Dr. Hafs suggested using the idea of control, and Ms. Cordle asked if, "control (or mitigate) adverse effects so that they are not significant" was what he had in mind. Dr. Hafs pointed out that the object of the experiment may be to get some adverse effect. It was agreed that "minimize" should be substituted for "prevent".

The committee then had a lengthy discussion on using the term "significant" to modify adverse effects. Mr. Stern reminded the committee that the legal basis for the term significant had been discussed previously and the decision was to leave it out.

Dr. LeTourneau said it is not enough to "minimize" adverse effects. Dr. Bulla suggested the second sentence read, "The level of safety concern is based on the organism's potential to cause significant adverse effects on health or on managed or natural ecosystems and on appropriate management practices." Dr. Tolin said this was much better and suggested that,"the availability of" be added before "appropriate".

The group next discussed revisions for Section VI-D-1. Mr. Stern pointed out that in the original version the language was "virtually no potential for adverse effects". Dr. Tolin said that going from five levels to three doesn't require inserting "significant." Mrs. Cordle asked whether we are only concerned with adverse effects that are "significant", and pointed out that if "significant" is dropped, an organism with adverse effects, even if not significant, could not be Level 1. Dr. Tolin said she would not interpret it that way. Dr. Bulla said he did not think dropping "significant" made Level 1 more stringent, and said any adverse effect on human health would be significant. Dr. Hafs agreed, because almost by definition, an adverse effect is significant. Mr. Stern said there is definitely a difference between "significant adverse effects" and "adverse effects", but not so much difference in "virtually no potential for adverse effects," and "preventing significant adverse effects". There was general agreement to not use the term "significant" and affirmation that ABRAC preferred language more comparable to that in the published Guidelines.

Dr. Flamm asked for clarification on whether the committee felt there was a difference between "virtually no potential for adverse effects" and "virtually no potential for significant adverse effects." He said he thought one was much stronger than the other. Mr. Stern said whether or not there was a difference, it was the option chosen. Dr. Tolin said the question is whether the choice results in fewer organisms being classified as Level 1. Dr. Flamm asked, "Is there a microorganism that has virtually no potential for adverse effect? Dr. Tolin replied, "yes", and Dr. Kemp cited Rhizobium.

Dr. Bulla asked that the term "attributes" be flagged, and terms such as "traits" or "characteristics" be used instead. Ms. Cordle pointed out that changes all throughout the document and Appendix I would be needed if that word were changed. Dr. Tolin said "attributes" was a carefully chosen word; Dr. Vidaver agreed.

Before discussing the changes proposed in Section VI-D-1, Ms. Cordle flagged a problem to the group; namely, the substitution of "standard agricultural research practices" for "standard agricultural practices" in the revision discussed the previous day. She said the problem is that it implies that research practices in use may not conform with the safety level of the organism. Dr. Hafs by way of clarification said by defining what we want people to do in addition to good agricultural research practices, we are saying the good agricultural research practices now are not very good. Dr. Bulla said it would be wrong to tie level one to "farming practices".

Dr. Barbosa said, when one looks at examples of what good research practices are, in Appendix 2, they relate to the experimentation and not safety, with the exception of the last example given. Dr. Kemp replied that the intent was to indicate that an experiment done at Level 1 is of such low concern that we haven't asked the researcher to do anything in addition to what is outlined for Level 1.

Ms. Cordle asked whether instead of relating Level 1 to "good agricultural research practices" we relate it to "reproductive or physical isolation beyond that which is standard agricultural practice." Dr. Tolin suggested using terms, e.g., "even if dissemination is uncontrolled or unmanaged beyond the use of standard agricultural practices." She said Level 1 corresponds to the use of no special measures to prevent dissemination. Dr. Bulla again pointed out that the research being done might not relate to agricultural practices, but to ecological research, for example.

Dr. Kemp turned the group's attention to the list of attributes in Section VI-D-1. Ms. Cordle explained that the two attributes suggested for deletion, Sections VI-D-1-f and g, are no longer relevant if we are saying that these organisms are not a problem even if disseminated. Dr. Kemp agreed. She also asked whether under VI-D-1-c, replication should be added to survival. Mr. Stern questioned the need for any change in the attributes originally listed.

A new Section VI-D-2-a through VI-D-2-e was presented by Ms. Cordle, but time prevented discussion. Dr. Kemp suggested the working group revisit the suggested revisions and advise Ms. Cordle. In discussing revised Section VI-D-3-a through VI-D-3-f, the committee agreed that the original sections (previously relating to Level 5) should be retained. Any problems can be ironed out by the Working Group.

Dr. Kemp turned the discussion to revisions for Section VII and asked that particular comments be directed to Ms. Cordle, OAB, or the Working Group. Dr. Bollinger questioned whether the section was too focused on process. Dr. Bulla flagged a concern in the second paragraph of Section VII about "molecular characterization" and how extensive the characterization should be.

Next the Committee considered the revisions for Table 1, Appendix 1.

After discussion of Ms. Cordle's revisions, Dr. Bollinger asked if the Competitiveness Council would be commenting on the Guidelines. When Mr. Stern replied yes, Dr. Bollinger suggested that the ABRAC might not want to spend too much time editing the Guidelines.

Dr. Kemp asked if the Africanized honeybee featured in Appendix 1 and Table 1, Appendix 1 should be replaced. He also asked if the examples in Appendix 1 should be carried through all the way to determining appropriate confinement procedure(s).

It was agreed that carrying the examples through the steps would be helpful. The examples, as appropriate will be sent to the authors requesting revision.

Dr. Sorensen suggested that the parasitic wasp example developed by Dr. Fred Gould be substituted for the Africanized honeybee, and that the pine tree example (from the original 12 examples) be added to the 5 examples in Table 1, Appendix 1. The ABRAC agreed to Dr. Sorensen's suggestion. Drs. Sorensen and LeTourneau agreed to rewrite Dr. Gould's wasp example. Dr. Whitmore suggested that an expert from the southern United States rewrite the pine example.

Dr. Bollinger pointed out that the aquatic organisms section in Appendix 2 had ignored algae. Dr. Kemp asked if someone could write something on fish or algae for the Guidelines. Dr. Tolin said that she could contact Dr. Eric Hallerman of her institution in that regard.

The ABRAC voted unanimously to accept Dr. Kemp's motion.

Potential Applications of Biosensors to Agriculture

Dr. Osburn introduced Capt. Warren Schultz, U.S. Naval Research Laboratory. Along with his colleagues, Drs. Frances Ligler and James Campbell, Capt. Schultz discussed how research on biosensors that they recently conducted could be applied to agricultural biotechnology.

Capt. Schultz explained that biosensors are detection systems that use a biomolecule or a biomimetic to recognize a substance of interest. Biosensors already are being used to detect illegal drugs such as cocaine, and a DNA-based biosensor could be used for risk analysis and plant biotechnology.

Capt. Schultz and his colleagues promised to make their material available in printed form to the ABRAC at a later time.

After the presentation, the ABRAC recessed for lunch at 12:30 p.m., and Dr. Osburn reconvened the meeting at 1:38 p.m.

Report by Performance Standards Working Group

Dr. Osburn asked Dr. Whitmore to report on the efforts of the Performance Standards Working Group established the previous day.

Dr. Whitmore reported the Working Group's recommendation that in order for an institution to carry out its responsibilities regarding biotechnology research it must:

1) Maintain an awareness of all research at the institution involving field testing of genetically modified organisms;

2) Develop a knowledge of all applicable regulations and requirements for this research;

3) Possess the scientific and technical ability to evaluate proposed experiments and the adequacy of proposed confinement actions; and

4) Provide mechanisms for informing the public community of the institution's actions under guidelines and regulations and for eliciting public response.

Bearing those four points in mind, Dr. Whitmore proposed that the performance standards read as follows:

> Each institution conducting or sponsoring agricultural research involving USDA funds in the field testing of genetically modified organisms is responsible for safe research. Fulfilling this responsibility requires at least the following activities:
>
> a. Establishment and implementation of policies that include confirmation that the organisms used and the conditions of research are assessed in accordance with the principles of the USDA Guidelines.
>
> b. Ensuring that all principal investigators responsible for agricultural research involving field testing of genetically modified organisms comply with the USDA

Guidelines and appropriate regulations, and assisting them in doing so.

c. Ensuring that concerns of the community about field testing of genetically modified organisms are solicited and addresssed by the institution.

Dr. Kemp moved that the performance standards, together with incorporation of the four points as a preamble, be accepted by the ABRAC. Dr. Sorensen seconded the motion and the Committee passed it unanimously.

Additional Changes to the Guidelines

Dr. Vidaver moved that the phrase "genetically modified organisms" be substituted for the phrase "organisms with deliberately modified hereditary traits" in the title of the Guidelines and throughout the document. Dr. LeTourneau seconded the motion, and it passed unanimously.

Dr. Vidaver moved that the phrase "planned introduction" be retained in the title of the Guidelines, even though some of the public comments suggested that the phrase "field testing" be substituted. Dr. Tolin seconded the motion, and it passed unanimously.

Comments on CSRS/NEPA Proposal

Dr. Osburn asked Dr. Jones to summarize the public comments on the CSRS Agency Procedures to Implement the National Environmental Policy Act (NEPA) published in the Federal Register (56 FR 8156, February 27, 1991).

Dr. Jones explained that a CSRS NEPA regulation was needed because the USDA regulations regarding NEPA are very general and not very informative about agricultural research.

The proposal established a number of proposed categorical exclusions to NEPA, and generally described activities for which environmental assessments (EA's) and environmental impact statements (EI's) may be needed.

Dr. Jones said the proposal elicited nine comments. Five came from academia, three came from environmental groups, and one was from a Federal agency. The comments concerned the following issues:

- the use of agency funds for needed environmental documentation;

- appeal procedures for handling conflicts in interpreting NEPA;

- the addition of historical and archaeological resources to the list of circumstances that would trigger exceptions to categorical exclusions;
- the scope of the categorical exclusions;
- the exclusion for contained research;
- the development of EA's for all field work that releases toxic chemicals or genetically modified organisms;
- the exclusion for renovation, rehabilitation, or revitalization of physical facilities;
- the cumulative impact of programs that eventually have commercial applications;
- CEQ regulations as the basis for proposing an exception for substantial controversies based on environmental grounds;
- the need for an EA on the proposed regulation itself;
- the proposal's public participation features;
- the scientific integrity of the process;
- deletion of the phrase "control agents"; and
- the paperwork load on scientists.

Dr. Jones said a CSRS committee is in the process of reviewing the comments, drafting responses, and preparing the final regulation. Some of the comments, he said, will be incorporated into the final regulation. A preamble discussing the comments is likely to appear in the final regulation, he added.

OAB Update

Dr. Jones then updated the ABRAC on OAB activities. He said that the USDA Biotechnology Council (a subcommittee of the interagency Committee on Biotechnology and Agriculture) is working with USDA Consumer Advisor Ann Chadwick on ways to inform consumers about biotechnology. The Council hopes to complete its recommendations in September.

Dr. Jones displayed a copy of Biotechnology at USDA, a new overview of biotechnology activities prepared by OAB public affairs specialist Marti Asner. He also mentioned the Kiawah Island conference proceedings discussed earlier by Dr. MacKenzie had been published.

Ms. Cordle described a recent inspection of the Auburn research ponds by herself and a scientific team. Three construction items were incomplete. A few days later, a local APHIS official followed up on the inspection and found that those three items had been satisfactorily completed. CSRS Administrator Dr. John Patrick Jordan approved the addition of fish to the ponds on May 21, and the fish were added May 22.

Dr. Jones reported that financial constraints may not permit another meeting of the full ABRAC before October 1, although a working group could meet before that time. He also mentioned that the National Agricultural Biotechnology Council would be meeting in Sacramento, CA, from May 30 through June 1.

Dr. Tolin said that the NIH Recombinant DNA Advisory Committee (RAC) would be meeting May 30 and 31. One of the agenda items deals with changes in the NIH Guidelines regarding deliberate release of organisms. She said the RAC will also consider eliminating the requirement of RAC review of releases.

Concluding Business

Dr. Osburn recommended that the Classification and Confinement Working Group be kept intact to help OAB rework the Guidelines in light of the public comments, and that Dr. Kemp remain as chair. He suggested that Dr. Jones and Dr. Alvin Young decide how the Group should continue to function. The ABRAC agreed to Dr. Osburn's recommendation.

Dr. Osburn recommended that the Risk Assessment Priority Setting Subcommittee remain intact. Conflicts in members' schedules had prevented the subcommittee from meeting in May as planned, but Dr. Osburn said the subcommittee still could be active and begin receiving background information that would enable members to start thinking about the subject. The ABRAC agreed to the recommendation.

Dr. Jones reiterated that Dr. Young has discussed the possibility of a full ABRAC meeting in October. Dr. Tolin asked that a date be set soon so that scheduling conflicts could be avoided.

Dr. Osburn thanked the OAB staff, Dr. Hess and Ms. Zannoni, and members and visitors for participating in the meeting. He adjourned the meeting at 2:30 p.m.

Susan McCullough
Rapporteur

Daniel Jones, Editor and
Acting Executive Secretary

Bennie Osburn
Chair

APPENDIX A

LIST OF VISITORS PRESENT

Paul Cooley, Dynamac, Inc.
Margriet Caswell, USDA, Economic Research Service
Edward D. Bruggeman, National Audubon Society
Sally McCammon, USDA, Animal and Plant Health Inspection Service
David MacKenzie, USDA, Cooperative State Research Service
Stanley Pierce, Rivkin, Radler, Bayh, Hart & Kremer, Uniondale, NY
Marshall Phillips, USDA, Agricultural Research Service
Jay Blowers, USDA, Cooperative State Research Service
Ray Dobert, Office of Sen. Tom Daschle
David Johnson, Senate Agriculture Committee
Eric Flamm, Food and Drug Administration
Lisa Zannoni, USDA Science and Education
Jane Rissler, National Wildlife Federation
Charles Hess, USDA Science and Education
Margaret Mellon, National Wildlife Federation
Chuck Kastner, USDA Animal and Plant Health Inspection Service
Pedro Barbosa, University of Maryland
Cathy Joyce, USDA Animal and Plant Health Inspection Service
Larry Zeph, Environmental Protection Agency
Elizabeth Milewski, Environmental Protection Agency
Warren Schultz, U.S. Naval Research Laboratory
James Campbell, U.S. Naval Research Laboratory
Frances Ligler, U.S. Naval Research Laboratory

APPENDIX B

Recommended Changes in the Guidelines

for Section VI-D and Section VII.

Section VI-D. 1st para., 2nd sentence. Change to read:

> The level of safety concern is based on the potential for significant adverse effects on human health or on managed or natural ecosystems and the level of confinement necessary to prevent significant adverse effects.

Section VI-D. 3rd para. Delete

Section VI-D-1. Level 1. Substitute the following:

> Organisms whose attributes in the specified accessible environment are sufficiently well understood so that it can be determined with reasonable certainty that the organism has no potential for significant adverse effects on human health or on managed or natural ecosystems. Standard agricultural research practices, as defined in Section IX-C-1, are sufficient to prevent significant adverse effects. Some attributes that alone or in combination might indicate Level 1 organisms are:

Section VI-D-1 a. No history of significant adverse effects in the accessible environment or similar environments.

Section VI-D-1-b. Low evolutionary potential to become a harmful organism in the accessible environment.

Section VI-D-1-c. Low probability of survival in the accessible environment beyond the time necessary for the particular research.[1]

Section VI-D-1-d. Low probability of exchange of genetic information with native populations of organisms, or low probability that any exchange would cause significant adverse effects, or

Section VI-D-e. Indigenous status in the accessible environment.

Section VI-D-(f. and g.) Delete

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[1] Should the attribute address proliferation?

Section D-2. Level 2.

Organisms that have a potential for significant adverse effects on human health or on managed or natural ecosystems. Testing outside a contained facility can be managed to prevent any significant adverse effects but requires confinement measures beyond the use of standard agricultural research practices. Some of the attributes that alone or in combination might indicate Level 2 organisms are:

VI-D-2-a. History of significant adverse effects in the accessible environment or in similar environments.

VI-D-2-b. Ability to survive and proliferate in the accessible environment.

VI-D-2-c. Potential for exchange of genetic information with native populations.

VI-D-2-d. Existence of practical techniques to minimize the dissemination of viable organisms beyond the research site and thereby eliminate any potential for significant adverse effects, or

VI-D-2-e. Existence of practical techniques to recapture or kill and escaped organisms before significant adverse effects can occur.

VI-D-3. Level 3.

Organisms that have a potential for significant adverse effects on human health or on managed or natural ecosystems. For these organisms it cannot be determined with reasonable certainty that the potential for significant adverse effects can be adequately managed or controlled outside a contained facility. Some of the attributes that alone or in combination might indicate a Level 3 organisms are:

VI-D-3-a. History of significant adverse effects in the accessible environment or in similar environments.

VI-D-3-b. Ability to survive and proliferate in the accessible environment.

VI-D-3-c. Non-indigenous status in the accessible environment.

VI-D-3-d. High frequency of genetic exchange with native populations of organisms

VI-D-3-e. Lack of effective techniques to minimize escape of viable organisms from the research site and prevent significant adverse effects, or insufficient information about the organism

to reasonably predict that available techniques are adequate for prevent significant adverse effects if tested outside a contained facility.

D-3-f. Lack of adequate techniques to recapture or kill escaped organisms before significant adverse effects occur.

VI-D-(4 and 5) Delete

VII. Step 2: Determination of the Effect of the Genetic Modification on Level of Safety Concern.

The genetic modification should be evaluated to determine what changes, if any, the modification has on the attributes previously determined for the parental (unmodified) organism. Genetic modification may have no effect on the level of safety concern for the organism, or it may increase or decrease the level of safety concern. The effects of the genetic modification on safety must be evaluated with reference to (1) the direct actions of the organism *per se* on human health or on managed or natural ecosystems, (2) indirect actions of the organism through the substances it produces, and (3) effects resulting from exchange of genetic material with native populations.

In Step 2, principal investigators should examine information on the method used to modify the organism, including information, as appropriate, on parentage, or on the donor organism and any vector system used for the transformation; the molecular characterization and stability of the modified genetic material; and gene expression, functions, regulation, and effects. Although the process of modification alone is not a determinant of safety, information about the process can be useful in predicting phenotypic attributes of the modified organism that are important in determining safety. The available information allows a determination of whether the genetic modification decreases the level of safety concern (Type 1) for the modified organism, has no effect on the level of safety concern (Type 2), or increases the level of safety concern (Type 3).

VII-A. Type 1: *Genetic Modifications that Decrease the Level of Safety Concern for the Modified Organisms*

Type 1 modifications include those which delete or disrupt expression of a gene(s) known to be responsible for traits such as pathogenicity, fertility, survival, or fitness in ways that both increase safety and change the level of confinement necessary to prevent significant adverse effects. Modifications that only increase safety but don't

change the level of confinement necessary would not decrease the level of safety concern.

VII-B. Type 2: *Genetic Modifications That Have No Effect on the Level of Safety Concern for the Modified Organism*

Type 2 modifications include:

VII-B-1.

Genetic modifications that have no phenotypic consequence(s) in the field, e.g., certain marker genes bearing no hazardous traits, and

VII-B-2

Genetic modifications that have a known or predictable phenotypic consequence(s) in the field that is unlikely to result in additional, significant adverse effects or require a change in level of confinement to prevent significant adverse effects, e.g., a storage protein gene with a more desirable amino acid balance.

VII-C. Type 2: *Genetic Modifications That Increase the Level of Safety Concern for Modified Organism*

Type 3 modifications include:

VII-C-1.

Genetic modifications that affect the expression of genes, their function, regulation or effects, and which are not sufficiently well understood to reasonably predict that the level of confinement necessary to prevent significant adverse effects for the parental (unmodified) organism is also adequate for the modified organism.

* U.S. G.P.O.:1991-311-403:40094/CSRS